

REMARKS

Claims 1, 4-19, 32 and 43-50 were examined in the Office Action under reply and stand rejected solely under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. This rejection is believed to be overcome for reasons discussed below.

Applicants note with appreciation the withdrawal of the previous rejection under 35 U.S.C. §103(a). However, the Examiner states: "Should Applicant obviate the following new rejection under 35 U.S.C. 112, first paragraph (new matter rejection) the rejection of claims 1, 4-19 and 32 under 35 U.S.C. 103(a) will be reinstated and applied to new claims 43-50." Office Action, page 2. Applicants submit that reinstating the rejection as proposed by the Examiner is wholly improper for the following reasons. Moreover, should the Examiner decide on reinstating the rejection, finality of this Office Action must be withdrawn.

In particular, 37 CFR §1.113(b) states that in making a final rejection "the examiner shall repeat or state all grounds of rejection then considered applicable to the claims in the application, clearly stating the reasons in support thereof." As explained in MPEP §706.07, the purpose for this mandate is to bring "prosecution to as speedy conclusion as possible and at the same time to deal justly by both the applicant and the public." Thus, references that can be applied should be fully applied. Moreover, MPEP §706.07 states "in making the final rejection, all outstanding grounds of rejection of record should be carefully reviewed, and any such grounds relied on in the final rejection should be reiterated. They must also be clearly developed to such an extent that applicant may readily judge the advisability of an appeal unless a single previous Office action contains a complete statement supporting the rejection."

The Office has failed to follow these mandates. The Office expressly states that the §103(a) rejection has been **withdrawn**. By threatening reinstatement of the rejection, the Examiner is unduly prolonging prosecution. As explained above, this is completely improper. Should the Examiner decide to reinstate the rejection, and apply the same to claims 43-50, finality of this Office Action **must** be withdrawn. Additionally, the basis for relying on the references against amended claims 1, 4-19 and 32, and new claims 43-50, must be set forth with

particularity in order to give applicants a full and fair opportunity to address the same. Failure to do so will constitute an abridgment of applicants' Due Process rights.

Rejection Under 35 U.S.C. §112, First Paragraph:

Claims 1, 4-19, 32 and 43-50 were rejected under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. The Examiner contends there is no written support for an isolated polypeptide having a deletion of "the amino acid sequence corresponding to amino acids 1027-1241 of HCV-1." However, applicants believe the claims are fully supported by the specification as filed and that the written description requirement of 35 U.S.C. §112, first paragraph is indeed satisfied.

In order to comply with the written description requirement, an applicant's specification must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, i.e., whatever is now claimed. *Vas Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991) (cited in MPEP § 2163 and in the Examiner Guidelines on Written Description Requirement). There is no *in haec verba* requirement. See, e.g., *Vas Cath*, 19 USPQ2d at 1116; *Martin v. Johnson*, 172 USPQ 391, 995 (CCPA 1972), stating: "the description need not be in *ipsis verbis* (i.e., "in the same words") to be sufficient." Thus, newly added claim limitations may be supported in the specification through express, implicit or inherent disclosure. Moreover, the Examiner has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. *In re Wertheim*, 191 USPQ 90 (CCPA 1976) (cited in MPEP § 2163.04 and in the Examiner Guidelines on Written Description Requirement). Applying these tenets, applicants submit that the Office has failed to carry its burden and that the present claims indeed comply with the written description requirement of 35 U.S.C. §112, first paragraph.

Contrary to the Office's assertions, the particular deletion recited in the claims is indeed found in the specification as filed. The Examiner's attention is directed to page 11, line 20, as well as page 58, line 8, which explains that delNS3-5 (the amino acid sequence of which is shown in Figure 5) includes amino acids 1242-3011. As recognized by the Examiner, the specification further explains at page 27, line 30 that the full-length NS3 protein spans 1027-

1657. Moreover, NS4 occurs at positions 1658-1972, NS5a at positions 1973-2420 and NS5b at positions 2421-3011, numbered relative to HCV-1. Thus, taken together, it is readily apparent that the deletion present in NS3 spans amino acid 1027 (the N-terminus of NS3) to amino acid 1241, as claimed. Indeed, contrary to the Examiner's assertion, the sequences shown in Figures 5, 11, 14, 17, 18, 21 and 22 all include a deletion of amino acids 1027-1241 from NS3. One of skill in the art need only compare the known sequence of the HCV-1 NS3 region with the mutant NS3 sequences present in each of these depicted constructs to determine that this is in fact the deletion that is present in the various constructs.

Thus, should this rejection be maintained, applicants request that the Patent Office provide specific evidence as to why "persons skilled in the art would not recognize in [an] applicant's disclosure a description of the invention defined by the claims," *In re Wertheim*, 191 USPQ 90 (CCPA 1976). Without such evidence, this rejection cannot be maintained. Accordingly, withdrawal thereof is respectfully requested.

CONCLUSION


Applicants respectfully submit that the claims are patentable over the art. Accordingly, allowance is believed to be in order and an early notification to that effect would be appreciated.

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